FEB 1 6 2001

K002466
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Section II
Summary and Certification
510K Summary of Safety and Efficacy
ACTICOAT™ Composite Dressing

August 9, 2000

1. Submitter

Westaim Biomedical, Inc
One Hampton Rd. Suite 302
Exeter, NH 03833

Steve Chartier
Manager, Regulatory and Clinical Affairs
(603) 775-7300

2. Device Name

Proprietary Name:	ACTICOAT™ Composite Dressing
Common Name:	Dressing
Classification Name:	Dressing
Regulatory Class:	OTC

3. Intended Use

Over-the-counter Indications: Local management of superficial wounds, minor burns, abrasions and lacerations.

4. Device Description

Acticoat™ Composite Dressing is a 3-ply dressing consisting of an absorbent rayon core with an upper layer of polyurethane film and a lower layer of silver-coated high density polyethylene mesh designed to be a barrier against microbial infections of a wound. The silver in the coating is an alloy of silver and oxygen. The coating is highly porous, and the film has enhanced solubility in water-based fluids. Additionally, the performance characteristics of the Acticoat™ Composite Dressing are similar to those found in untreated gauze-based dressings in the areas of absorptivity and moisture content, abrasion testing, adhesion, and tensile strength.

The dressing will be sold in a variety of sizes the size used will depend on the size of the wound. The smallest dressing size will be 2" x 2" while the largest will be a 4" x 48" roll.

How Supplied

2" x 2"	(5 cm x 5 cm)
4" x 4"	(10 cm x 10 cm)
4" X 8"	(10 cm x 20 cm)

5. Predicate Device Comparison

The predicate devices also provide the same or similar functions, characteristics, and accessories as described above for the Acticoat™ Composite Dressing.

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The table below compares the features and characteristics of the Acticoat™ Composite Dressing to the predicate products.

Comparison of the ACTICOAT™ Contact Layer Dressing to Predicate Products

	Acticoat™ Composite Dressing	Acticoat™ Composite Wound Dressing (K983833)	Silverlon™ Adhesive Strips (K984205)
INTENDED USE			
Wound Dressing	Yes	Yes	Yes
DESIGN			
HDPE Skin Contact Layer	Yes	Yes	No
Absorbable	Yes	Yes	Yes
Antimicrobial silver coating	Yes	Yes	Yes
MATERIALS			
	HDPE	HDPE	Nylon

6. Biocompatibility

The biocompatibility of Acticoat™ Composite Dressing has been demonstrated through appropriate *in vivo* and *in vitro* tests as shown in the Acticoat Composite Wound Dressing (K983833).

7. Performance Data

The Acticoat™ Composite Dressing is identical to the Acticoat™ Composite Wound Dressing and as such has been subjected to the following performance tests:

- Silver dissolution
- Absorptivity and moisture content
- Drop penetration and vapor transmission
- Tensile strength
- Biocompatability studies (including skin irritation, sensitization and cytotoxicity
- Silver ion exposure levels
- *In vitro* studies of antimicrobial activity

In all instance, the Acticoat™ Composite Dressing is both effective for its intended use and functions in a substantially equivalent manner to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 1 6 2001

Mr. Steve Chartier
Manager, Regulatory and Clinical Affairs
Westaim Biomedical, Inc.
One Hampton Road, Suite 302
Exeter, New Hampshire 03833

Re: K002466
Trade Name: Acticoat™ Composite Dressing
Regulatory Class: I
Product Code: MGQ, KMF
Dated: November 20, 2000
Received: November 20, 2000

Dear Mr. Chartier:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Mark N. Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications For Use
Device Name: **ACTICOAT™ Composite Dressing**
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The Acticoat™ Composite Dressings is intended for use in the local management of superficial wounds, minor burns, abrasions and lacerations.

(Please do not write below this line - Continue on another page if necessary)
Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Milhouse

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K002466

Prescription Use_____ OR Over-the-Counter Use_____
(Per 21 CFR §801.109)

(Optional Format 1-2-96